Distr.
GENERAL

ECE/SC.TECH./40/Add.29
15 March 1994

ENGLISH
Original: FRENCH

SENIOR ADVISORS TO ECE GOVERNMENTS
ON SCIENCE AND TECHNOLOGY

INVENTORY OF EXISTING SAFETY GUIDELINES IN BIOTECHNOLOGY

MONOGRAPH

Information transmitted by the Government of Switzerland

SUMMARY OF SUBMISSION

None

LIST OF DOCUMENTS TRANSMITTED TO THE SECRETARIAT AND AVAILABLE FOR CONSULTATION ON REQUEST

(a) Guidelines for the use of genetically modified organisms, Swiss Interdisciplinary Committee for Biosafety in Research and Technology (SCBS), August 1993 (see Appendix I);

(b) Handbook II of the Industrial Accident Ordinance, Federal Office of the Environment, Forests and the Countryside, February 1992 (see Appendix II);

(c) Coordination of legislation on genetic engineering and medical methods of assisted procreation, Report of the Interdepartmental Working Group on Genetic Engineering, January 1993.

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Appendix I

GUIDELINES FOR THE USE OF GENETICALLY MODIFIED ORGANISMS *

Swiss Interdisciplinary Committee for Biosafety in Research
and Technology (SCBS)

August 1993

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Chapter 1	Principles and general considerations
Chapter 2	Safety assessment and the classification of work in genetic engineering
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Appendix II	Parameters for safety assessment of small-scale genetic engineering activities
Appendix III	Parameters for safety assessment of large-scale genetic engineering activities
Appendix IV	Micro-organisms of risk category 1
Appendix V	Classification of important micro-organisms and cell lines in risk categories 2 to 4
Appendix VI	Safety measures for genetic engineering activities in an enclosed environment

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* These guidelines are based on the Guidelines of the National Institutes of Health (United States of America, 1986), the Directives of the Council of the European Communities, German legislation on gentics and documents published by

OECD. As far as possible, these guidelines are compatible with Manual II of the Order on major accidents.

Appendix VII — Biological confinement systems

Appendix VIII — Notification and registration of genetic engineering projects with SCBS

Appendix IX — Information to be submitted with applications for experimental use of genetically modified organisms in an open environment

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Appendix II

HANDBOOK II OF THE INDUSTRIAL ACCIDENT ORDINANCE

Guidelines for enterprises using micro-organisms

Federal Office of the Environment, Forests and the Countryside

February 1992

The present Handbook II of the Industrial Accident Ordinance contains explanatory material and specifications regarding the rules governing the confined use of micro-organisms. Its purpose is therefore to supplement Handbook I of the Industrial Accident Ordinance, which was published in October 1991, and deals with chemical risks associated with fixed installations.

This document is based on a detailed report prepared by Holinger AG, Dübendorf, under a consultancy contract. A large number of other documents were taken into consideration, as were the new guidelines of the Swiss Interdisciplinary Committee for Biosafety in Research and Technology (SCBS), European Community Directive 90/219/EEC, commentaries on the German legislation governing genetic engineering and French AFNOR standards. Other major contributions included those of our many interlocutors in the Confederation and cantons, industry and science who placed their knowledge and experience at our service. We are deeply grateful to all of them.

This version of the Handbook is only provisional. Although it is the product of assiduous dialogue and reflection, too many points remain unclear for lack of practical experience. By force of circumstances, the final version will have to await experience acquired through practice in dealing with concrete cases; in its present form, the Handbook is intended as a set of clues that may help us to achieve some measure of consensus. We are particularly eager to keep in touch with all parties concerned with these questions. With the benefit of their assistance, practical experience and clearer bearings, Handbook II could be redrafted within the next year or two.

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